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PTO/SB/21 (02-04)

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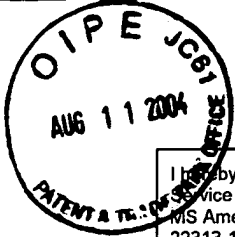
TRANSMITTAL FORM (to be used for all correspondence after initial filing)		Application Number	10/815,910
		Filing Date	March 30, 2004
		First Named Inventor	David M. Hadley
		Art Unit	3762
		Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	8*	Attorney Docket Number	330498002US

ENCLOSURES (Check all that apply)		
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Firm or Individual name	PERKINS COIE LLP Paul T. Parker - 38,264
Signature	<i>Paul Parker</i>
Date	August 9, 2004

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Dated: August 9, 2004

Signature: Stephen P. Whelan
(Stephen P. Whelan)

Docket No.: 330498002US
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

David M. Hadley and
Mustafa H. Sagioglu

Application No.: 10/815,910

Con. No.: 9281

Filed: March 30, 2004

Art Unit: 3762

For: METHODS FOR QUANTIFYING THE
MORPHOLOGY AND AMPLITUDE OF
CARDIAC ACTION POTENTIAL
ALTERNANS

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
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Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

A copy of each reference on the PTO/SB/08 is attached.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0665, under Order No. 330498002US.

Dated: *August 9, 2004*

Respectfully submitted,

By *Paul Parker*

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PTO/SB/08a/b (08-03)

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Substitute for form 1449A/B/PTO			Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Application Number	10/815,910 - Conf. No. 9281
			Filing Date	March 30, 2004
			First Named Inventor	David M. Hadley
			Art Unit	3762
			Examiner Name	Not Yet Assigned
			Attorney Docket Number	330498002US
Sheet	1	of	4	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		ACKERMAN, et al., "Ion Channels - Basic Science and Clinical Disease," New England Journal of Medicine, vol. 336 (22), pp. 1575-1586, 1977	
		ADAM, et al., "Estimation of Ventricular Vulnerability to Fibrillation Through T-Wave Time Series Analysis," Computers in Cardiology, pp. 307-310, September 1981	
		ADAM, et al., "Fluctuations in T-Wave Morphology and Susceptibility to Ventricular Fibrillation," Journal of Electrocardiology, vol. 17(3), pp. 209-218, 1984	
		ADAM, et al., "Ventricular Fibrillation and Fluctuations in the Magnitude of the Repolarization Vector," Computers in Cardiology, pp. 241-244, 1982	
		CARSON, et al., "Characterisation of unipolar waveform alternation in acutely ischaemic porcine myocardium," Cardiovascular Research, vol. 20, pp. 521-527, 1986	
		CHINUSHI, et al., "Electrophysiological Basis of Arrhythmogenicity of QT/T Alternans in the Long-QT Syndrome - Tridimensional Analysis of the Kinetics of Cardiac Repolarization," Circulation Research, vol. 83 (6), pp. 614-628, Sept 21, 1998	
		CINCA, et al., "Mechanism and Time Course of the Early Electrical Changes During Acute Coronary Artery Occlusion - An Attempt to Correlate the Early ECG Changes in Man to the Cellular Electrophysiology in the Pig," Chest, vol. 77, pp. 499-505, April 1980	
		COETZEE, et al., "Effects of thiol-modifying agents on K _{ATP} channels in guinea pig ventricular cells," American Journal of Physiology, vol. 38, pp. H1625-H1633, 1995	
		CORONEL, et al., "Reperfusion arrhythmias in isolated perfused pig hearts - Inhomogeneities in extracellular potassium, ST and TQ potentials, and transmembrane action potentials," Circulation Research, vol. 71 (5), pp. 1131-1142, Nov 1992	
		DEMIDOWICH, et al., "Electrical alternans of the ST segment in non-Prinzmetal's angina," PACE, vol. 3, pp. 733-736, Nov.-Dec. 1980	
		Di BERNARDO, et al., "Effect of changes in heart rate and in action potential duration on the electrocardiogram T wave shape," Abstract only, Physiol Meas, vol. 23 (2), pp. 355-364, May 2002	

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	DUCKETT, et al., "Modeling the Dynamics of Cardiac Action Potentials," Physical Review Letters, vol. 84 (4), pp. 884-887, July 24, 2000	
	GIMA, et al. "Ionic Current Basis of Electrocardiographic Waveforms – A Model Study," Circulation Research, vol. 90, pp. 889-896, May 2002	
	HAN, "Ventricular vulnerability during acute coronary occlusion," American Journal of Cardiology, vol. 24, pp. 857-864, December 1969	
	HAN, et al., "Temporal dispersion of recovery of excitability in atrium and ventricle as a function of heart rate," American Heart Journal, vol. 71 (4), pp. 481-487, April 1966	
	HASHIMOTO, et al., "Effects of calcium antagonists on the electrical alternans of the ST segment and on associated mechanical alternans during acute coronary occlusion in dogs," Circulation, vol. 68 (3): 667-672, Sept. 1983	
	HASHIMOTO, et al., "Effects of the ventricular premature beat on the alternation of the repolarization phase in ischemic myocardium during acute coronary occlusion in dogs," Abstract only, Journal of Electrocardiology, vol. 17 (3), pp. 229-238, July 1984	
	HELLERSTEIN, et al., "Electrical alternation in experimental coronary artery occlusion," American Journal of Physiology, vol. 160, pp. 366-374, Feb. 1950	
	KASS, et al., "Channel structure and drug-induced cardiac arrhythmias," PNAS, vol. 97 (22), pp. 11683-11684, October 24, 2000	
	KAŽIĆ et al., "Ion Channels and Drug Development - Focus on Potassium Channels and Their Modulators," Medicine and Biology, Vol 6 (1), pp. 23 - 30, 1999	
	KLEINFELD, et al., "Alternans of the ST Segment in Prinzmetal's Angina," Circulation, vol. 55 (4), pp. 574-577, April 1977	
	KLEINFELD, et al., "Electrical alternans of components of action potential," American Heart Journal, vol. 75 (4), pp. 528-530, April 1968	
	KONTA, et al., "Significance of discordant ST alternans in ventricular fibrillation," Circulation, vol. 82 (6), pp. 2185-2189, Dec. 1990	
	KUBOTA, et al., "Role of ATP-Sensitive K ⁺ Channel of ECG ST Segment During a Bout of Myocardial Ischemia - A Study of Epicardial Mapping in Dogs," Circulation, vol. 88 (4, Part 1), pp. 1845-1851, Oct. 1993	

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		KURZ, et al., "Ischaemia induced alternans of action potential duration in the intact-heart: dependence on coronary flow, preload and cycle length," European Heart Journal, vol. 14, pp. 1410-1420, 1993	
		LUKAS, et al., "Differences in the electrophysiological response of canine ventricular epicardium and endocardium to ischemia: Role of the transient outward current," Circulation, vol. 88 (6), pp. 2903-2915, Dec.1993	
		MOODY, et al., "Clinical Validation of the ECG-Derived Respiration (EDR) Technique," Computers in Cardiology, pp. 507-510, 1986	
		NAKASHIMA, et al., "Experimental studies and clinical report on the electrical alternans of ST segment during myocardial ischemia," Japanese Heart Journal, vol. 19 (3) pp. 396-408, May 1978	
		NEARING, et al., "Dynamic Tracking of Cardiac Vulnerability by Complex Demodulation of the T Wave," Science, vol. 252, pp. 437-440, April 1991	
		NEARING, et al., "Modified moving average analysis of T-wave alternans to predict ventricular fibrillation with high accuracy," Journal of Applied Physiology, vol. 92, pp. 541-549, Feb. 2002	
		NEARING, et al., "Tracking States of Heightened Cardiac Electrical Instability by Computing Interlead Heterogeneity of T-Wave Morphology Using Second Central Moment Analysis," J Appl Physiol, vol. 95, pp. 2265-2272, Dec 2003., 41 pages (First published August 1, 2003; 10.1152/jappphysiol.00623.2003)	
		PASTORE, et al., "Mechanism Linking T-Wave Alternans to the Genesis of Cardiac Fibrillation," Circulation, vol. 99, pp. 1385-1394, Mar. 1999	
		RAEDER, et al., "Alternating Morphology of the QRST Complex Preceding Sudden Death," New England Journal of Medicine, vol. 326 (4), pp. 271-272, Jan. 23, 1992	
		RING, et al., "Exercise-Induced ST Segment Alternans," American Heart Journal, vol. 111 (5), pp. 1009-1011, May 1986	
		RODEN, et al., "Cardiac Ion Channels," Annual Review Physiology, vol. 64, pp. 431-475, 2002	
		SALERNO, et al., "Ventricular arrhythmias during acute myocardial ischaemia in man. The role and significance of R-ST-T alternans and the prevention of ischaemic sudden death by medical treatment," European Heart Journal, vol. 7 Suppl A, pp. 63-75, 1986	
		SCHRAM, et al., "Differential Distribution of Cardiac Ion Channel Expression as a Basis for Regional Specialization in Electrical Function," Circulation Research, vol. 90, pp. 939-950, May 2002	

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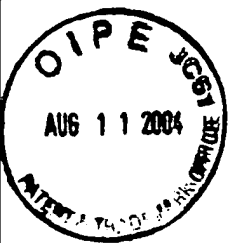
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		SMITH, et al., "Electrical Alternans and Cardiac Electrical Instability," Circulation, vol. 77 (1), pp. 110-121, Jan. 1988	
		SMITH, et al., "Subtle Alternating Electrocardiographic Morphology as an Indicator of Decreased Cardiac Electrical Stability," Computers in Cardiology, pp. 109-112, 1985	
		VERRIER, et al., "Risk Identification by Noninvasive Markers of Cardiac Vulnerability," Foundations of Cardiac Arrhythmias-Basic Concepts and Clinical Approaches, P. Spooner and M. Rosen (eds.), Marcel Dekker, Inc., pp. 745-777, 2000	
		VERRIER, et al., "Electrophysiologic Basis for T Wave Alternans as an Index of Vulnerability to Ventricular Fibrillation," Journal of Cardiovascular Electrophysiology, Vol. 5, pp. 445-461, May 1994	
		WALKER, et al., "Repolarization alternans: implications for the mechanism and prevention of sudden cardiac death," Abstract only, Cardiovascular Research, vol. 57 (3), pp. 599-614, Mar. 2003	
		WAYNE, et al., "Exercise-induced ST segment alternans," Chest, vol. 83 (5), pp. 824-825, May 1983	

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